DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2227–FN]

Medicare and Medicaid Programs; Approval of Deeming Authority of the Accreditation Commission for Healthcare (ACHC) for Home Health Agencies

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This notice announces our decision to approve the Accreditation Commission for Healthcare (ACHC) for recognition as a national accreditation program for home health agencies seeking to participate in the Medicare or Medicaid programs.

DATES: *Effective Date:* This final notice is effective February 24, 2006 through February 24, 2009.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786–0310.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a Home Health Agency (HHA) provided certain requirements are met. Sections 1861(o) and 1891 of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as an HHA in the Medicare program. The regulations at 42 CFR part 484 specify the conditions that an HHA must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for home health care. Regulations concerning provider agreements are at 42 CFR part 489, and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. Regulations concerning eligibility for home health and certain payment requirements are at 42 CFR part 409, Subpart E.

Generally, to enter into an agreement, a HHA must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 484 of our regulations. Then, the HHA is subject to regular surveys by a State survey agency to determine whether it continues to meet those requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(b)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accreditation organization that all applicable Medicare conditions are met or exceeded, we would ''deem'' those provider entities as having met the requirements. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation.

If an accreditation organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accreditation organization applying for approval of deeming authority under part 488, subpart A must provide us with reasonable assurance that the accreditation organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions.

II. Deeming Applications Approval Process

Section 1865(b)(3)(A) of the Act provides a statutory timetable to ensure that our review of deeming applications is conducted in a timely manner. The Act provides us with 210-calendar days after the date of receipt of an application to complete our survey activities and application review process. Within 60 days of receiving a completed application, we must publish a notice in the **Federal Register** that identifies the national accreditation body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish an approval or denial of the application.

III. Proposed Notice

On September 23, 2005, we published a proposed notice (70 FR 55862) announcing the Accreditation Commission for Healthcare's (ACHC's) request for approval as a deeming organization for HHAs. In the proposed notice, we detailed our evaluation criteria. Under section 1865(b)(2) of the Act and our regulations at § 488.4 (Application and reapplication procedures for accreditation organizations), we conducted a review of the ACHC application in accordance with the criteria specified by our regulation, which include, but are not limited to the following:

- An onsite administrative review of ACHC's (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and (5) survey review and decision-making process for accreditation.
- A comparison of ACHC's HHA accreditation standards to our current Medicare HHA conditions for participation.
- A documentation review of ACHC's survey processes to:

+ Determine the composition of the survey team, surveyor qualifications, and the ability of ACHC to provide continuing surveyor training.

+ Compare ACHC's processes to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

+ Evaluate ACHC's procedures for monitoring providers or suppliers found to be out of compliance with ACHC program requirements. The monitoring procedures are used only when the ACHC identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7(d).

+ Assess ACHC's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

+ Establish ACHC's ability to provide us with electronic data in ASCII-comparable code and reports necessary for effective validation and assessment of ACHC's survey process.

+ Determine the adequacy of staff and other resources.

+ Review ACHC's ability to provide adequate funding for performing required surveys.

+ Confirm ACHC's policies with respect to whether surveys are announced or unannounced.

+ Obtain ACHC's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(b)(3)(A) of the Act, the September 23, 2005 proposed notice (70 FR 55862) also solicited public comments regarding whether ACHC's requirements met or exceeded the Medicare conditions of participation for HHAs. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between the ACHC's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements

We compared the standards contained in ACHC's accreditation manual for

HHAs and its survey process in ACHC's Surveyor Training Manual with the Medicare HHA conditions for participation and our State Operations Manual. Our review and evaluation of ACHC's deeming application, which were conducted as described in section III of this final notice yielded the following:

- To meet the full intent of all Medicare standards and conditions, ACHC crosswalked the corresponding Medicare standard to each of its standards and stated that HHAs undergoing a deemed status survey from ACHC would meet the ACHC standard as well as the corresponding Medicare standard.
- ACHC added time frames to respond to complaints in all categories listed in its complaint process.
- ACHC revised its survey procedures to add triggers for identification of Immediate Jeopardy and the guidelines to determine when Immediate Jeopardy is removed.
- ACHC amended its guidelines for determining survey frequency for HHAs in accordance with the State Operations Manual (SOM) 2195.
- In order to be consistent with our policy, ACHC modified the language in its policies to state that Branch Office Additions must first be approved by the CMS Regional Office before scheduling a survey.
- ACHC modified its policies to conform with our standards in SOM 2200 that HHAs applying for an initial certification survey provide care to at least 10 patients and that 7 of those 10 are still active at the time of the initial survey.
- To meet our standards listed in SOM 2200C4, ACHC amended its policies to include criteria necessary for the required number of home visits required during the survey.
- ACHC developed a systematic way to ensure that the appropriate number of active and closed records was reviewed for the size of the facility being surveyed in order to meet the standards listed at SOM 2200C5.
- ACHC established a new policy that requires all deemed HHAs to submit a Plan of Correction for all deficiencies identified.
- A new policy was developed by ACHC concerning the qualifications and training necessary for lead surveyors.
- ACHC will implement an annual training program for all its surveyors and incorporate a measurement tool that evaluates effectiveness of training.
- To meet the requirements listed in § 488.4(b)(3)(v), ACHC established a policy that permits its surveyors to serve as witnesses if we take an adverse action based on accreditation findings.
- ACHC revised its policies to eliminate pre-survey contact and notification of surveyors to HHAs in order to meet our requirements of fully unannounced HHA surveys.

B. Term of Approval

Based on the review and observations described in section III of this final notice, we have determined that ACHC's requirements for HHAs meet or exceed our requirements. Therefore, we recognize the ACHC as a national accreditation organization for HHAs that request participation in the Medicare program, effective February 24, 2006 through February 24 2009.

V. Collection of Information Requirements

This final notice does not impose any information collection and record-keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA.

VI. Regulatory Impact Statement

We have examined the impact of this final notice as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 98–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The RFA requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, States and individuals are not considered small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any notice that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we consider a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

This final notice recognizes ACHC as a national accreditation organization for HHAs that request participation in the Medicare program. There are neither significant costs nor savings for the program and administrative budgets of Medicare. Therefore, this final notice is not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866. We have determined, and the Secretary certifies, that this final notice will not result in a significant impact on a substantial number of small entities and will not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

In an effort to better assure the health, safety, and services of beneficiaries in HHAs already certified as well as provide relief to State budgets in this time of tight fiscal restraints, we deem HHAs accredited by ACHC as meeting our Medicare requirements. Thus, we continue our focus on assuring the health and safety of services by providers and suppliers already certified for participation in a cost-effective manner.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget. In accordance with Executive Order 13132, we have determined that this final notice will not significantly affect the rights of States, local or tribal governments.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb)

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare Hospital Insurance Program; and No. 93.774, Medicare—Supplemental Medical Insurance Program)

Dated: January 30, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 06–1650 Filed 2–23–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

Notice of Hearing: Reconsideration of Disapproval of Iowa State Plan Amendments 05–003

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing to be held on April 13, 2006, at the Richard Bolling Federal Building, 601 E. 12th Street, Room 235, Kansas City Conference Room, Kansas City, MO 64106–2898, to